

March 7, 2001

LuAnn Maloney
FMC Corporation
Agricultural Products Group
1735 Market Street
Philadelphia, PA 19103

Dear Ms. Maloney:

Thank you for FMC's submission of two single chemicals to the RTK HPV Challenge Program. EPA has conducted a preliminary review of the submissions and will post them on the program's Web site. However, we note that the test plans for 3-chloro-2-methylpropene (CAS No. 563473) and 2,3-dihydro-2,2-dimethyl-7-benzofuranol (CAS No. 1563388) include prospective mammalian testing for one and five SIDS endpoints, respectively.

As you know, EPA has highlighted animal welfare considerations in its approach to the Challenge Program. As described in a recent Federal Register notice entitled "Data Collection and Development of HPV Chemicals" (65 FR 81686), EPA has asked that sponsors observe a number of principles included in a letter to sponsor companies dated October 14, 1999 (<http://www.epa.gov/chemrtk/ceoltr2.htm>) (enclosure). It is the intention of the Agency that the HPV Challenge program should proceed in a manner consistent with this guidance.

The above guidance touches on several points relevant to your proposals as follows. Participants are asked to defer animal testing on individual chemicals (i.e., those not part of a category) until November, 2001. Participants are also encouraged to use *in vitro* genetic toxicity testing to generate any needed genetic toxicity screening data unless experimental limitations preclude that approach. Finally, be advised that dermal toxicity testing is not included in the voluntary HPV Challenge Program.

EPA requests that FMC consider these concerns and advise the Agency within 30 days of any modifications to its submission.

The HPV Challenge is a voluntary program whose successful implementation will depend upon the good faith effort and cooperation of all parties. We appreciate the spirit of cooperation and commitment that has characterized this initiative to date.

Thank you again for your commitment to participate in the HPV Challenge program. If you wish further clarification, please contact Rich Hefter at 202-260-3470 or visit the Web site at www.epa.gov/chemrtk.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

cc: W. Sanders
C. Auer

Enclosure